

Serial No.: 10/762,552

**REMARKS**

Claims 1 - 15 and 17 - 33 remain pending in the present application. Claim 16 has been canceled and the subject matter thereof has been incorporated into independent claim 1. Claims 15, 17 - 19, 22, 24 - 26, 29 and 30 have been amended to conform with the amendment to claim 1 and the cancellation of claim 16. No new matter has been introduced by the above-amendment.

Entry of the above-amendment is respectfully requested. The amendment places the allowable subject matter of claim (16) into independent form. No new issues, further search, or additional consideration are required by entry of the claim amendment. And the amendment places the application into condition for allowance and/or in better condition for appeal. Accordingly, entry of the above-amendment is appropriate and is respectfully requested.

**Rejection Under § 112, 2<sup>nd</sup> paragraph**

Claims 1-15 and 30 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

Regarding claims 1-15, the Examiner has failed to state how the claims are indefinite and thus has not met his burden in making a rejection. 35 USC § 8 does not place any burden or requirement on the patent applicant. To the contrary, § 8 permits the Director to maintain and revise a classification schedule. It is not possible for a claim to be rejected under § 8, and certainly not logical for a claim to be held indefinite for a purported failure to comply with § 8. Indeed, there is no requirement under 35 U.S.C. that the claims recite a structural formula or that the claims be drafted so as to assist the

Serial No.: 10/762,552

Examiner's search of the prior art. See *Ex parte Tanksley*, 37 USPQ2d 1382 (BPAI 1994); *Ex parte C*, 27 USPQ2d 1492 (BPAI 1992). Claim 1, both before and after the present amendment, reasonably conveyed the scope of the subject matter that applicants' regarded as their invention. Accordingly, this rejection is improper.

Nonetheless, to expedite prosecution and in the spirit of cooperation, applicants have amended claim 1 by incorporating allowable claim 16 therein. Thus, this aspect of the rejection has been rendered moot.

Regarding claim 30, the Examiner has failed to state why the claim is indefinite or ambiguous and thus no basis for rejection under § 112, second, has been set forth. Instead the Examiner essentially alleges that the step of "converting" the compound into a pharmaceutically acceptable salt is too broad; i.e. lacks enablement. This is incorrect.

Claim 30 simply recites the ubiquitous and common practice of forming a pharmaceutically acceptable salt of a known pharmaceutical. Indeed, Coates et al. (US 4,695,578) claimed all physiologically acceptable salts of the compound of instant formula (1) as well as other compounds. Thus, since at least the late 1980's, the average artisan has known how to make salts of the instant compound of formula (1). The conditions under which a base can be turned into a salt are many, and they are well known and/or readily determined without undue experimentation by the skilled chemist. There is no reason to limit the claimed conversion to a salt by conditions of temperature or pH as the Examiner suggests; nor is there any need to limit the claim under the patent law. Claim 30 depends upon allowable claim 1, and thus is patentable over the prior art. The full scope of the claim is reasonably enabled, especially given the simplicity of the

Serial No.: 10/762,552

conversion and the skill in the art (Coates et al., etc.), and thus is in compliance with § 112, first paragraph.

Finally, as to whether a positive step is recited, the Examiner has already identified the step; naming the step of "converting." Such a step embraces any way of chemically transforming compound (1) into a pharmaceutically acceptable salt. There is nothing unclear about the meaning of such a step or the scope of this process claim.

In view of the above, all claims reasonably define the scope of the subject matter to be patented and are thus in full compliance with § 112, second paragraph.

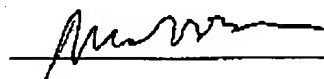
Reconsideration and withdrawal of this rejection are requested.

#### Conclusion

In view of the above arguments, the presently claimed subject matter is novel and patentable. Reconsideration and withdrawal of the rejection and allowance of the present application are respectfully requested.

Should the Examiner have any questions regarding this application, he is encouraged to contact Mark R. Buscher (Reg. No. 35,006) at telephone No. 703 753 5256.

Respectfully submitted,



Mark R. Buscher Reg. No. 35,006

P.O. Box 161  
Catharpin, VA 20143  
703 753 5256